

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/501,566	Art Unit:	tba
Filed:	07/15/2004	Examiner:	tba
1 <sup>st</sup> Inventor:	UNO, Yumiko	Allowed:	
For:	Novel Proteins and DNAs Thereof	Batch:	
Atty. Dkt. No.	3015 USOP	Paper No.:	

**CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10**

USPS EXPRESS MAIL LABEL. No. EV 524905265 US

DATE IN: July 21, 2005

**Itemized Papers/Items:**

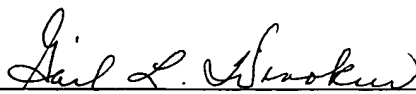
1. This Certificate of Express Mailing and Return Postcard (2 pages)
2. Transmittal Form (1 page X 2)
3. Response to Notice to Comply with Sequence Listing Requirements (3 pages), Submission of CRF of Sequence Listing (53 pages), IBM PC/AT format disk containing the CRF of the Sequence Listing,
4. Copy of Notification to Comply mailed 02/09/2005 (2 pages).
5. Copy of Notification of Defective Response mailed 07/13/2005 (2 pages)
6. Copy of Notification of Defective Response with Raw Sequence Listing Error Report, mailed 07/11/2005 (22 pages)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP SEQUENCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on this date, 7/21/05

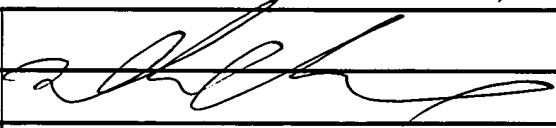
Dated: 7/21/05

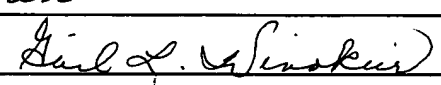
  
Gail L. Winokur

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/501/566	
	Filing Date	07/15/2004	
	First Named Inventor	UNO, Yumiko	
	Art Unit	tba	
	Examiner Name	tba	
Total Number of Pages in This Submission	86	Attorney Docket Number	3015 USOP

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Postcard; Certificate of Express Mailing Sequence Listing Requirements; disk Copies of Notifications
Remarks The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 500799.		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm Name		
Signature		
Printed name	Mark Chao, Ph.D., JD	
Date	7/21/05	Reg. No. 37,293

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: <u>Express</u>		
Signature		
Typed or printed name	Gail L. Winokur	Date 7/21/05

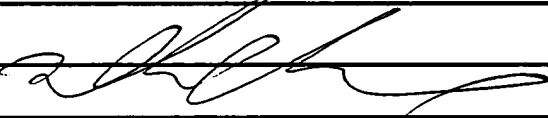
This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

*Express Mail to EV 52490526545*

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/501/566	
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	First Named Inventor	UNO, Yumiko	
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Remarks The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 500799.		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm Name		
Signature		
Printed name	Mark Chao, Ph.D., JD	
Date	7/21/05	Reg. No. 37,293

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: <u>Express</u>			
Signature			
Typed or printed name	Gail L. Winokur	Date	7/21/05

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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*Express Mail to EV 524905265 US*

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Application No.:	10/501,566	Art Unit:	tba
Filed:	07/15/2004	Examiner:	tba
1 <sup>st</sup> Inventor:	UNO, Yumiko	Allowed:	
For:	Novel Proteins and DNAs Thereof	Batch:	
Atty. Dkt. No.	3015 US0P	Paper No.:	

**Response to Notice to Comply with Sequence Listing Requirements**  
**Notice of Defective Response**

**MAIL STOP SEQUENCE**

Commissioner for Patents  
P.O. Box 1450  
Arlington, VA 22313-1450

Sir:

This is in response to the Notice of Defective Response (Mailed 7/13/2005) regarding Applicants reply to the Notice of Missing Requirements mailed 2/09/2005.

Applicants wish to clarify the record for the purposes of determination of any Administrative delays.

**The Original Notice to Comply with Sequence Listing Requirements only requested a replacement CRF disk from the Applicants, and did NOT provide an error report.**

The original Notice to Comply with Sequence Listing Requirements mailed 2/09/2005 (Copy Enclosed), stated that the CRF disk was missing or damaged, and that a replacement CRF must be sent to comply.

In the Applicant's response mailed, 3/29/2005, a replacement CRF disk was provided. Thus the response was in fact not defective in any way as the Applicants provided each and every response requested in the Notice.

**Two Notice of Defective Response have been sent to Applicant**

In the same mailing, two (2) Notice of Defective Response have been mailed, one dated 7/11/2005 and one dated 7/13/2005. For the purpose of this reply, Applicants will use the date of 7/13/2005 as the official Mailing Date.

**The Notice of Defective Response mailed 7/13/2005 was the first time any Sequence Listing Error Report was provided to the Applicants, and for the first time, an Error Report dated 7/22/2004.**

The Notice of Defective Response (Mailed 7/13/2005) provided as an enclosure a copy of a sequence listing error report dated 7/22/2004. This had never before been provided to the Applicants, and is not referenced in the original Notice of to Comply with Sequence Listing Requirements.

Also attached to the Notice of Defective Response (Mailed 7/13/2005), was a second sequence listing error report dated 5/16/2005 in which the Examiner has written that "Same Errors as Previous Submission".

Since the Applicants were not provided with any error report to correct in the Original Notice, and were only requested to supply a replacement CRF disk, it is no wonder that the errors are the same.

**The Notice of Defective Response dated 7/11/05 or 7/13/2005 do not refer to any defects in the Sequence Listing or reference the Sequence Listing Error Reports provided, but once again recite that the CRF is either missing or damaged and unreadable.**

Since the Applicants were provided with two complete Sequence Listing Error Reports, it is difficult to understand the request to resubmit a CRF because the original CRF was damaged or unreadable. However, Applicants herewith respond to the Notice as if it were complete and referenced errors in the Sequence Listing.

**A delay due to Sequence Listing Compliance has been caused by USPTO error and mishandling of the application materials of at least 5 Months and 4 days.**

Since the original Notice to Comply mailed 2/9/2005 should have been accompanied with the Sequence Listing Error Report dated 7/22/04, and in fact the CRF was not damaged or

missing, Applicants have been delayed in making corrections to the Sequence Listing from 2/9/2005 to 7/13/2005.

**Submission in Reply to Current Notice**

In order to comply with the current sequence listing rules, Applicants respectfully submit, along with a copy of the Original Notice and Current Notice, a substitute written Sequence Listing and a DOS Text CRF Sequence Listing file "3015us0p.seq.txt" on the enclosed 3.5" IBM PC/AT computer disk.

Applicants also submit herewith copies of:

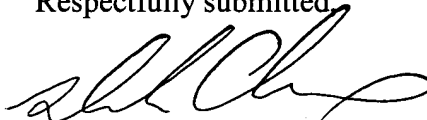
1. Original Notice to Comply (2/9/2005)
2. Notice of Defective Response (7/11/2005)
3. Notice of Defective Response (7/13/2005)
4. Sequence Error Report (5/16/05)
5. Sequence Error Report (7/22/04)

Please substitute the Written Sequence Listing for the Sequence Listing as filed.

The undersigned hereby certifies that the CRF and the written Sequence Listing identical in content. The Sequence Listing contains no new matter.

Consideration of the application and claims on the merits is solicited. Early allowance of the claims is requested. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, she is respectfully invited to call applicants' attorney.

Respectfully submitted,



Dated: July 20, 2005

(847)383-3372

(847)383-3391

Mark Chao, Ph.D., Reg. No. 37,293

Elaine M. Ramesh, Ph.D., Reg. No. 43032

Attorney for Applicants

Customer No. 23115

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA



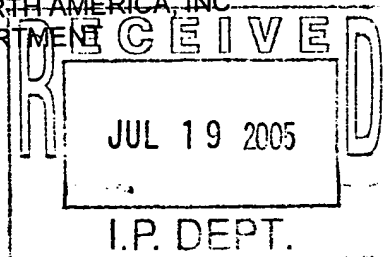
# UNITED STATES PATENT AND TRADEMARK OFFICE

327  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/501,566	FIRST NAMED APPLICANT Yumiko Uno	ATTY. DOCKET NO. 3015 USOP
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INTERNATIONAL APPLICATION NO. PCT/JP03/003111	
IA. FILING DATE 01/16/2003	PRIORITY DATE 01/18/2002

23115  
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069



CONFIRMATION NO. 8263  
371 FORMALITIES LETTER  
\*OC000000016461299\*

Date Mailed: 07/13/2005

## NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495)

- Priority Document
- Copy of the International Application filed on 07/15/2004
- English Translation of the IA filed on 07/15/2004
- Copy of the International Search Report filed on 07/15/2004
- Preliminary Amendments filed on 07/15/2004
- Information Disclosure Statements filed on 07/15/2004
- Biochemical Sequence Diskette filed on 03/29/2005
- Oath or Declaration filed on 07/15/2004
- Biochemical Sequence Listing filed on 07/15/2004
- U.S. Basic National Fees filed on 07/15/2004
- Assignment filed on 07/15/2004
- Priority Documents filed on 07/15/2004

Applicant's response filed 03/29/2005 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS mailed 02/09/2005 have not been completed.

- The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d). Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR

1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

INDIA L EVANS

Telephone: (703) 308-9140 EXT 212

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/501,566	PCT/JP03/00311	3015 USOP





## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
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 Alexandria, Virginia 22313-1450  
 www.uspto.gov

307

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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23115  
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 LINCOLNSHIRE, IL 60069

INTERNATIONAL APPLICATION NO.
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PCT/JP03/00311

I.A. FILING DATE	PRIORITY DATE
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01/16/2003

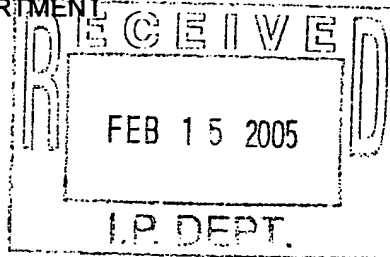
01/18/2002

CONFIRMATION NO. 8263

371 FORMALITIES LETTER



\*OC000000015073078\*



Date Mailed: 02/09/2005

### NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

The following items **MUST** be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):
  - The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
  - APPLICANT MUST PROVIDE:
    - An initial or substitute computer readable form (CRF) of the "Sequence Listing."
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
  - For Rules Interpretation, call (703) 308-4216
  - To Purchase PatentIn Software, call (703) 306-2600
  - For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

INDIA L EVANS

Telephone: (703) 308-9140 EXT 212

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.

10/501,566

INTERNATIONAL APPLICATION NO.

PCT/JP03/00311

ATTY. DOCKET NO.

3015 USOP

FORM PCT/DO/EO/922 (371 Formalities Notice)



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INDIA L EVANS

Telephone: (703) 308-9140 EXT 212

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FORM PCT/DO/EO/916 (371 Formalities Notice)